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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,609	12/17/2001	Richard L. Vandlen	P0712C5	5365
23552	7590	04/05/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			HAYES, ROBERT CLINTON	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,609	VANDLEN ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,39-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1/8/04 & 12/17/01</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 1/08/04 has been entered.
2. This application still fails to comply with the requirements of 37 CFR 1.821 through 1.825 because 37 CFR 1.821 (a)(2)(c-d) states that *each sequence disclosed must appear separately in the "Sequence listing" and in the text of the description* and claims whenever described. In particular, the appropriate SEQ ID NO remains not recited on page 36 (line 6). See MPEP 2422 & 2431.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). Note that failure to respond to both the requirements for sequence compliance and the Office action below will be held as nonresponsive, and may result in abandonment of this application.
3. The rejection of claim 20 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to the amendment of the claims to both structurally and functionally characterize the claimed antibodies.
4. Applicant's arguments filed 1/08/04 have been fully considered but they are not deemed to be persuasive.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 20 & 39-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 & 15-25 of U.S. Patent No. 5,859,206, for the reasons made of record in Paper NO: 8 (mailed 8/08/03).

7. Claims 20 & 39-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper NO: 8 (mailed 8/08/03), and as follows.

Applicants argue on pages 12-14 of the response that “[c]ompliance with the written description requirement does not require an applicant to describe exactly the subject matter claimed; rather, the description must clearly allow a person of ordinary skill in the art to recognize that he or she invented what was claimed”, that “Applicants have described a heregulin 2 α polypeptide both structurally and functionally”, and cites *Vas-Cath Inc. v. Mahurkar*, *Univ. of California v. Eli Lilly and Co*, *In re Wertheim*, *In re Kaslow* and *Amgen Inc. v. Chugai Pharmaceutical Co.* In contrast to Applicants' assertions, the claims still encompass “other animal species of HRG2- α polypeptides such as rabbit, rat, porcine, non-human primate, equine, murine, and ovine HRG2- α ... sequences”, as stated on page 14 of the specification, for which no written description exists. As Applicants correctly point out, the court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession of

the claimed invention [emphasis added].” However, the human heregulin 2 α polypeptide of SEQ ID NO:11 is not “rabbit, rat, porcine, non-human primate, equine, murine, and ovine HRG2- α ”. Therefore, it remains unknown and not described what structurally constitutes such polypeptides from any such different species, especially since it is not clear whether such polypeptides even exist in these different species; thereby, not reasonably meeting the written description requirements under 35 U.S.C. 112, first paragraph. See MPEP 2163.

Analogous to the situation decided in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), which held that “an adequate written description of a DNA [product] requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA [product] itself”. In addition, *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) then held that claims directed to mammalian FGF’s were found unpatentable due to lack of written description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only the single species of a human heregulin 2 α polypeptide of SEQ ID NO: 11 has been described in the instant specification. Accordingly,

“One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is”. *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997),

and that:

“A description of a genus of cDNAs [products] may be achieved by means of a recitation of a representative number of cDNAs [products], *defined by nucleotide sequence*, failing in the scope of the genus or of a recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus* [emphasis added]. This is analogous to enablement of a genus under 112, [first paragraph], by showing the enablement of a

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representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218”.

Thus, Applicants clearly are not in possession of the claimed genus at the time of filing the instant application, for the reasons made of record.

It is suggested that amending the claims to “binds to a human-isolated polypeptide that has... identity to the human heregulin 2 α [having an amino acid sequence] of SEQ ID NO: 11...” in claim 20 should obviate this rejection, and remove redundant claim language.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
March 31, 2004



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600